

**UNITED STATES DISTRICT COURT OF THE  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

**IN RE: DIGITEK PRODUCT LIABILITY  
LITIGATION**

**MDL NO. 1968**

*Case No.: 2:08-md-1968*

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Kathy McCornack, et al.  
Plaintiffs,

*Case No.: 2:09-cv-0671*

vs.

Actavis Totowa, LLC, et al.  
Defendants.

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Vega, et al.

*Case No. 2:09-cv-0768*

vs.

Actavis Totowa, LLC, et al.  
Defendants.

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**RELATED CASES**

**PLAINTIFFS' EXHIBITS IN OPPOSITION TO  
DEFENDANTS' MOTIONS FILED AUGUST 1-3, 2011**

Plaintiffs in the matter *Kathy McCornack, et al. v. Actavis, et al.*, Case No. 2-cv-0671, (“McCormack Plaintiffs” or “Plaintiffs”), hereby respectfully submit the attached exhibits in opposition to defendants’ motion for summary judgment in all of the MDL cases, (Doc. Nos. 523-524), motion to exclude plaintiffs’ general liability experts in all MDL cases, (Doc. Nos. 525-526), motion to exclude unreliable hearsay in all MDL cases (Doc. Nos. 527); motion to

exclude decedent Daniel McCornack's *post mortem* digoxin blood concentration in the *McCornack* action, (Doc. Nos. 120-121), motion to exclude plaintiffs' experts, Richard T. Mason, M.D., and Keith Gibson in the *McCornack* action, (Doc. Nos. 120-121), and motion for summary judgment in the *McCornack* action, (Doc. Nos. 120-121):

Exhibit No.	Description	Bates No.	Start Page
016	Plaintiffs' Deposition Exhibit 16 Investigation Log No. 07-093	ACTAV000003317-336 ACTAV000002598-613 ACTAV000002486 ACTAV000002615-622	000001
025	Plaintiffs' Deposition Exhibit 25 Revised Warning Letter dated Feb. 1, 2007 from FDA to Actavais	ACTAV000028242-248	000069
044	Plaintiffs' Deposition Exhibit 44 Incident Records, Nov. 30, 2007, Batch No. 70924A1	ACTAV000002757	000077
050	Plaintiffs' Deposition Exhibit 50 FDA Form 483, September 28, 2007	n/a	000079
052	Plaintiffs' Deposition Exhibit 52 QA Sampling Records, Batch No. 70670A	ACTAV000049220-226	000083
068	Plaintiffs' Deposition Exhibit 68 FDA Form 483, August 10, 2006	n/a	000091
073	Plaintiffs' Deposition Exhibit 73 Quality Review Board Minutes, Jan. 26, 2009	ACTAV000443062-098	000101
079	Plaintiffs' Deposition Exhibit 73 FDA Form 483, Feb. 08, 2006	ACTAV00002890... [partially illegible]	000139
080	Plaintiffs' Deposition Exhibit 80 FDA Establishment Inspection Report, July 21, 2008	ACTAV000429520-535	000147

Exhibit No.	Description	Bates No.	Start Page
082	Plaintiffs' Deposition Exhibit 82 Complaint for Permanent Injunction, Nov. 14, 2008, <i>U.S. v. Actavis Totowa, LLC, et al.</i> Doc. No. 1, Case No. 2:08-cv-05656-SDW-MCA	n/a	000164
090	Plaintiffs' Deposition Exhibit 90 FDA Establishment Inspection Report, July – August 2006	n/a	000182
091	Plaintiffs' Deposition Exhibit 91 FDA Establishment Inspection Report, March – May 2008	n/a	000225
097	Plaintiffs' Deposition Exhibit 97 Email dated Dec. 18, 2007 re Investigation No. 07-093	ACTAV000408864	000321
113	Plaintiffs' Deposition Exhibit 113 “Urgent: Drug Recall” notice dated April 24, 2008	ACTAV000526961-969	000323
120	Plaintiffs' Deposition Exhibit 120 “Urgent: Drug Recall” notice dated April 28, 2008	UDLL000004006-008	000333
128	Plaintiffs' Deposition Exhibit 128 Investigation Final Report, Investigation No. 04-003	ACTAV001375829-833	000337
136	Plaintiffs' Deposition Exhibit 136 Final Corrective Action Memo, Audit XA-06-010, Jan. 23, 2008 (2006 Incident)	MLYN... [partially illegible]	000343
140	Plaintiffs' Deposition Exhibit 140 Email dated April 30, 2008 re Mylan/Bertek Quality Head	ACTAV00014215... [partially illegible]	000349
141	Plaintiffs' Deposition Exhibit 141 Investigation #08-060 Record, Batch No. 80228A1, April 1, 2008 Occurrence	ACTAV000928231	000352

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144	Plaintiffs' Deposition Exhibit 144 2008 Annual Product Review, Digoxin Tablets, USP - 0.125 mg	ACTAV000649134-148	000354
146	Plaintiffs' Deposition Exhibit 146 Email dated April 17, 2008 re Form 483 Items	ACTAV000429342	000370
157	Plaintiffs' Deposition Exhibit 157 FDA Form 483, Sept. 28, 2007	n/a	000373
158	Plaintiffs' Deposition Exhibit 158 FDA Establishment Inspection Report, Sept. 2007	n/a	000377
159	Plaintiffs' Deposition Exhibit 159 Blend Failure Investigation Report, Batch Nos. 70148A and 70207A	ACTAV000165623-630	000418
171	Plaintiffs' Deposition Exhibit 171 FDA Establishment Inspection Report, Sept. 2007	ACTAV000505260-300	000427
183	Plaintiffs' Deposition Exhibit 183 Email and Summary of Blend Failures 2007, July 20, 2007	ACTAV001423286-288	000469
214	Plaintiffs' Deposition Exhibit 214 Consent Decree of Permanent Injunction, Dec. 23, 2008, Doc. No. 4-2, Case No. 2:08-cv- 05656-SDW-MCA	n/a	000473
217	Plaintiffs' Deposition Exhibit 217 Email dated April 15, 2008 and Table Summarizing Investigations by Product	ACTAV000299883-889	000511
220	Plaintiffs' Deposition Exhibit 220 Health Hazard Evaluations, April 25, 2008	ACTAV000006569 ACTAV000006579-580	000519
227	Plaintiffs' Deposition Exhibit 227 Email dated May 3, 2008 re Digitek Tablet Presses	ACTAV000605912-913	000523

Exhibit No.	Description	Bates No.	Start Page
228	Plaintiffs' Deposition Exhibit 228 FDA Establishment Inspection Report, September – October 2006	ACTAV0000293... [partially illegible]	000526
229	Plaintiffs' Deposition Exhibit 229 FDA Warning Letter, Aug. 15, 2006	ACTAV000923261-264	000547
230	Plaintiffs' Deposition Exhibit 230 Amide Letter Response to FDA, dated Feb. 28, 2006, re FDA Form 483	ACTAV000923269-279	000552
231	Plaintiffs' Deposition Exhibit 231 FDA Warning Letter, Jan. 9, 2007	ACTAV00002882... [partially illegible]	000564
233	Plaintiffs' Deposition Exhibit 233 “Chronology of Actavis Totowa (formerly Amide) Regulatory Issues” Powerpoint, January 2007, and Email	MYLN000032351-359	000572
235	Plaintiffs' Deposition Exhibit 235 “Summary of FDA Inspectional History of Amide Pharmaceutical, Inc.”	ACTAV001087612... [partially illegible]	000582
236	Plaintiffs' Deposition Exhibit 236 FDA Form 483, Nov. 29, 2001, and Amide Response Letter, Dec. 10, 2001	ACTAV000568969-972	000593
241	Plaintiffs' Deposition Exhibit 241 Amide Letter, June 8, 2004, to Rite Aid, re Complaint #C04-016	ACTAV001316391	000598
242	Plaintiffs' Deposition Exhibit 242 Amide Letter, July 13, 2004, to Rite Aid, re Complaint #C04-018	ACTAV001316392	000600
246	Plaintiffs' Deposition Exhibit 246 FDA Warning Letter, Aug. 15, 2006	ACTAV000028926-928	000602
249	Plaintiffs' Deposition Exhibit 249 Email dated Oct. 1, 2007, re top products associated with death or permanent injury	ACTAV000561564-565	000606

Exhibit No.	Description	Bates No.	Start Page
253	Plaintiffs' Deposition Exhibit 253 2006 Annual Product Review, Digoxin Tablets, USP 0.25 mg	ACTAV000006437-442	000609
258	Plaintiffs' Deposition Exhibit 258 Email dated Jul. 12, 2006, re Digitek Tablet Presses	ACTAV000645033	000616
259	Plaintiffs' Deposition Exhibit 259 Email dated Jul. 21, 2006, re Digitek Tablet Presses, and quotation	ACTAV000645019-024	000618
M14	Plaintiffs' Deposition Exhibit M14 Email dated Jan. 4, 2008, re Digitek Parameter Review	MYLN000034729	000625
M21	Plaintiffs' Deposition Exhibit M21 Email dated Jan. 4, 2007 re Actavis-Digitek	MYLN000256375-376	000627
M25	Plaintiffs' Deposition Exhibit M25 Email dated April 27, 2008 re Actavis (Amide) Recall and FDA Inspection	MYLN000925874-875	000630
M30	Plaintiffs' Deposition Exhibit M30 Email dated May 6, 2008 re Digitek Tablets 05/06 Update	MYLN000041928-929	000633
M45	Plaintiffs' Deposition Exhibit M45 UDL Laboratories Memorandum dated Jan 21, 2008, re Actavis Totowa Re-Assessment Summary	UDLL000025489-490	000636
M64	Plaintiffs' Deposition Exhibit M64 Email dated Jul. 21, 2008 re Actavis Totowa Recall	MYLN000593691-692	000639
M65	Plaintiffs' Deposition Exhibit M65 UDI Laboratories, Product Receipt Records 2007, et al.	UDLL000005805-818	000642
M69	Plaintiffs' Deposition Exhibit M69 UDL Internal Investigation Records, May 2008	UDLL000004768-771	000657

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500	Plaintiffs' Exhibit 500 Expert Witness Report, Dr. David M. Bliesner, Ph.D.  500.1 – CV (000764)	n/a	000662
501	Plaintiffs' Exhibit 501 “302” Sample Batches with Questions Manufacturing Review	ACTAV001420149-151	000776
502	Plaintiffs' Exhibit 502 Actavis letter to FDA dated May 21, 2008	ACTAV00002826... [partially illegible]	000780
503	Plaintiffs' Exhibit 503 Phyllis Lambridis Deposition Transcript Jan. 18, 2010	n/a	000790
504	Plaintiffs' Exhibit 504 Recall Records Produced by CVS/Caremark	n/a	001190
505	Plaintiffs' Exhibit 505 Recall Notice dated April 28, 2008, Produced by Caremark	UDLL000004006-008	001217
506	Plaintiffs' Exhibit 506 Daniel McCornack Consumer-Level Recall Notice dated May 2, 2008, Produced by Caremark	n/a	001221
507	Plaintiffs' Exhibit 507 Deposition Transcript, Dr. David M. Bliesner, Ph.D., (Bliesner Depo I)  [Bates No. 001512-003039 Intentionally Omitted]	n/a	001224

Exhibit No.	Description	Bates No.	Start Page
508	Plaintiffs' Exhibit 508 Deposition Transcript, Dr. David M. Bliesner, Ph.D., Feb. 18, 2011, (Bliesner Depo II)  <i>[Bates No. 003127-003462 Intentionally Omitted]</i>  508.2 – Revised Transcript (003463)	n/a	003040
509	Plaintiffs' Exhibit 509 Deposition Transcript, Mark G. Kenny, June 29, 2010, (Kenny Depo I)  <i>[Bates No. 003941-004820 Intentionally Omitted]</i>	n/a	003864
510	Plaintiffs' Exhibit 510 Deposition Transcript, Mark G. Kenny, Feb. 16, 2011, (Kenny Depo II)  <i>[Bates No. 004893-008064 Intentionally Omitted]</i>	n/a	004821
511	Plaintiffs' Exhibit 511 Expert Witness Report and CV, Mark G. Kenny	n/a	008065
512	Plaintiffs' Exhibit 512 Deposition Transcript, James J. Farley, June 28, 2010, (Farley Depo I)  <i>[Bates No. 008200-008679 Intentionally Omitted]</i>	n/a	008116
513	Plaintiffs' Exhibit 513 Deposition Transcript, James J. Farley, Jan. 19, 2011, (Farley Depo II)  <i>[Bates No. 008834-009492 Intentionally Omitted]</i>	n/a	008680
514	Plaintiffs' Exhibit 514 Expert Witness Report and CV, James J. Farley	n/a	009493

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515	Plaintiffs' Exhibit 515 Deposition Transcript, Russell F. Somma, Ph.D., Jul. 1, 2010  [Bates No. 009823-009844 Intentionally Omitted]	n/a	009521
516	Plaintiffs' Exhibit 516 Expert Witness Report, Russell F. Somma, Ph.D.  516.1 – CV (009862)	n/a	009845
600	Plaintiffs' Exhibit 600 Lawrence E. Von Dollen, M.D., Deposition Transcript, October 5, 2009  600.1 – Exhibit 1 (009988) 600.2 – Exhibit 2 (009992)	n/a	009870
601	Plaintiffs' Exhibit 601 Gordon Lemm, M.D., Deposition Transcript, October 2, 2009  601.1 – Exhibit 1 (010099) 601.2 – Exhibit 2 (010102) 601.3 – Exhibit 3 (010109) 601.4 – Exhibit 4 (010115) 601.5 – Exhibit 5 (010118) 601.6 – Exhibit 6 (010122)	n/a	009995
602	Plaintiffs' Exhibit 602 Deposition Transcript Richard T. Mason, M.D., Oct. 1, 2009, ("Mason Depo I")  602.1 – Exhibit 1 (010176) 602.2 – Exhibit 2 (010268) 602.3 – Exhibit 3 (010276) 602.4 – Exhibit 4 (010278) 602.5 – Exhibit 5 (010281) 602.6 – Exhibit 6 (010295) 602.7 – Exhibit 7 (010298) 602.8 – Exhibit 8 (010350)	n/a	010180

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	602.9 – Exhibit 9 (010352) 602.10 – Exhibit 10 (010359) 602.11 – Exhibit 11 (010365) 602.12 – Exhibit 12 (010369) 602.13 – Exhibit 13 (010375) 602.14 – Exhibit 14 (010379)		
603	Plaintiffs' Exhibit 603 Richard T. Mason, M.D., Deposition Transcript, Aug. 11, 2011, ("Mason Depo II")  603.16 – Exhibit 16 (010493) 603.17 – Exhibit 17 (010500) 603.18 – Exhibit 18 (010506) 603.19 – Exhibit 19 (010511) 603.20 – Exhibit 20 (010528) 603.22 – Exhibit 22 (010544) 603.23 – Exhibit 23 (010559) 603.24 – Exhibit 24 (010582) 603.27 – Exhibit 27 (010586) 603.28 – Exhibit 28 (010609) 603.29 – Exhibit 29 (010620) 603.30 – Exhibit 30 (010622) 603.31 – Exhibit 31 (010624)	n/a	010383
604	Plaintiffs' Exhibit 604 Amy R. McMaster, M.D., Deposition Transcript, August 4, 2011  604.1 – Deposition Exhibits (010740) 604.2 - Reporter's Certification (011012)	n/a	010626
605	Plaintiffs' Exhibit 605 Expert Witness Report, Amy R. McMaster, M.D.	n/a	011014

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606	Plaintiffs' Exhibit 606 Deposition Transcript, Keith P. Gibson, June 14, 2011  606.A – Exhibit A (011323) 606.B – Exhibit B (011339)  606.C – Exhibit C (011362) 606.D – Exhibit D (011371) 606.E – Exhibit E (011377) 606.F – Exhibit F (011392) 606.G – Exhibit G (011405) 606.H – Exhibit H (011410) 606.I – Exhibit I (011417) 606.J – Exhibit J (011424)	n/a	011018
607	Plaintiffs' Exhibit 607 Expert Witness Report, Keith P. Gibson	n/a	011435
608	Plaintiffs' Exhibit 608 C. Alan Brown, M.D., Deposition Transcript, August 10, 2011  608.1 – Deposition Exhibits (011548) 608.2 - Reporter's Certification (011600)	n/a	011450
609	Plaintiffs' Exhibit 609 Kathy McCornack Deposition Transcript, Oct. 5, 2009  609.1 - Reporter's Certification (011767)	n/a	011602
610	Plaintiffs' Exhibit 610 Daniel McCornack, Jr., Deposition Transcript, May 17, 2011	n/a	011769
611	Plaintiffs' Exhibit 611 Ralph McCornack Deposition Transcript, May 17, 2011	n/a	011860

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612	Plaintiffs' Exhibit 612 William L. Galanter, M.D., Deposition Transcript, August 3, 2011  612.1 – Deposition Exhibits (012064) 612.2 - Reporter's Certification (012251)	n/a	011921
613	Plaintiffs' Exhibit 613 Kennon J. Heard, M.D., Deposition Transcript July 14, 2011  613.1 – Deposition Exhibits (012336) 613.2 - Reporter's Certification (012722)	n/a	012253
614	Plaintiffs' Exhibit 614 Edward J. Barbieri Deposition Transcript, November 19, 2010, in <i>Johnson v. Actavis Totowa, LLC, et al.</i> , Case No. CJ-2009-5292	n/a	012724
615	Plaintiffs' Exhibit 615 Edward J. Barbieri Deposition Transcript, July 11, 2011, in <i>McCormack v. Actavis Totowa, LLC, et al.</i> , Case No. 2:09-cv-0671  615.1 - Reporter's Certification (013102)	n/a	012898
616	Plaintiffs' Exhibit 616 Expert Report, Walter N. Kernan, M.D.	n/a	013104
617	Plaintiffs' Exhibit 617 Mylan Distribution Agreement	n/a	013134
618	Plaintiffs' Exhibit 618 McCormack Pill Bottle Photos	n/a	013198
619	Plaintiffs' Exhibit 619 Walter N. Kernan, M.D., Deposition Transcript, April 22, 2011  [Bates No. 013328- 013843 Intentionally Omitted]	n/a	013202

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620	Declaration of Dr. David M. Bliesner, Ph.D.	n/a	013844
621	Declaration of Reynolds Delgado, M.D.	n/a	013858
622	Expert Witness Report, Reynolds Delgado, M.D.	n/a	013875

Respectfully Submitted:

Dated: August 24, 2011

/s/ Don E. Ernst  
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